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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Date: August 20, 1999

MEMORANDUM

Subject: **PP8F5002.** Human Health Risk Assessment for **Spinosad** use on Cucurbit Vegetables, Legume Vegetables, Stone Fruits, Corn, Sorghum, and Wheat
DP Barcode: D249374 Submission Number: S548502
PRAT Case Number: 290544

PP9E6035. Human Health Risk Assessment for **Spinosad** use on Oats, Barley, Buckwheat, Rye, Pearl, Millet, Proso Millet, Grain Amaranth, Popcorn, Teosinte, Grass Forage, Fodder and Hay Crop Group, Nongrass Animal Feeds Crop Group, Watercress, Turnip Tops, Sugar Apple, Cherimoya, Atemoya, Custard Apple, Ilama, Soursop, Biriba, Lychee, Longan, Spanish Lime, Rambutan, Pulasan, Papaya, Star Apple, Black Sapote, Mango, Sapodilla, Canistel, Mamey Sapote, Avocado, Guava, Feijoa, Jaboticaba, Wax Jambu, Starfruit, Passionfruit, Acerola, White Sapote, Ti Palm, and Cilantro (leaf).
DP Barcode: D258000 Submission Number: S565774
PRAT Case Number: 292174 Class: Insecticide
40 CFR 180.495 Trade Name SpinTor (62719-294),
Caswell Number: None Success (62719-292),
PC Code: 110003 Tracer (62719-267)

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1.0 EXECUTIVE SUMMARY

In petition 8F5002, Dow AgroSciences has requested the establishment of permanent tolerances for spinosad in/on cucurbit vegetables (Crop Group 9), legume vegetables (Crop Group 6), stone fruits (Crop Group 12), and the cereal crops corn, sorghum, and wheat. Additionally, petition 9E6035 requests uses on oats, barley, buckwheat, rye, pearl millet, proso millet, grain amaranth, popcorn, teosinte, grass forage, fodder and hay crop group, nongrass animal feeds crop group, watercress, turnip tops, sugar apple, cherimoya, atemoya, custard apple, ilama, soursop, biriba, lychee, longan, spanish lime, rambutan, pulasan, papaya, star apple, black sapote, mango, sapodilla, canistel, mamey sapote, avocado, guava, feijoa, jaboticaba, wax jambu, starfruit, passionfruit, acerola, white sapote, ti palm, and cilantro (leaf). All are new uses for spinosad, which has tolerances published in 40 CFR 180.495 for a number of commodities. Uses are pending for the tuberous and corm vegetable crop subgroup (Crop Subgroup 1C; PP8E5034) and for a Section 18 use to control Mediterranean fruit fly (99DA0009), which would result in tolerances on all crop commodities not currently covered by published or other pending tolerances.

Spinosad is an insecticide consisting of two related spinosyn compounds, Factor A and Factor D. The two active ingredients are typically present at an 85:15 (A:D) ratio.

Toxicology studies did not identify acute dietary or short-term, intermediate-term, or chronic dermal or inhalation toxicity endpoints; thus these risk assessments are not required. Similarly, a carcinogenic risk assessment for spinosad is not required. The chronic dietary endpoint for spinosad comes from the chronic toxicity study in dogs (52 weeks) and is based on the occurrence of vacuolation in glandular cells (parathyroid) and lymphatic tissues, arteritis, and increases in serum enzymes such as alanine aminotranferase, and aspartate aminotransferase, and triglyceride levels at 8.46 mg/kg/day (LOAEL). The NOAEL from this study was 2.68 mg/kg/day resulting in an RfD of 0.027 mg/kg/day. The FQPA Safety Factor for spinosad was reduced to 1X (FQPA Safety Factor Committee, 4/26/99); thus, the chronic Population Adjusted Dose (cPAD) is also 0.027 mg/kg/day.

The nature of the residue for spinosad is adequately understood in both plants and animals. For all commodities, the residue of concern is parent spinosad (Factors A and D combined). Adequate enforcement methods for plants and animals have already been accepted by the Agency.

Application rates for spinosad are low. For most of the commodities in this petition, the application rate ranges from 0.023 to 0.094 lb ai/A, with total seasonal application not to exceed 0.45 lb ai/acre. The pre-harvest intervals range from 1 day to 4 weeks, depending on the crop. In field studies with soybean (5X application rate) residues in/on the seeds were less than the LOQ (0.016 ppm) for all samples; for corn [field (5X) and sweet (1X)], residues in/on the grain were below the data-collection method LOD (0.005 ppm) in/on all samples (memo, M. Doherty, DP Barcode D249374, 6/24/99). In other crops and commodities, finite residues of spinosad were

found. The requested use on cereal grains results in a need for increases in published ruminant commodity tolerances and new poultry commodity tolerances.

No data were submitted in support of 9E6035. HED has agreed to use previously submitted field trial data on similar crops and make other allowances to set tolerances for the commodities listed in 9E6035 (memos, G. J. Herndon, DP Barcode D252416, 2/23/99; D258329, 8/4/99; D258330, 8/5/99). Specifically, tolerances for oats, barley, buckwheat, and rye are translated from wheat (0.020 ppm); tolerances for pearl millet, proso millet, and grain amaranth come from sorghum (1.0 ppm); popcorn and teosinte come from corn (0.020 ppm); grass forage, fodder and hay crop group (Crop Group 17) and nongrass animal feeds crop group (Crop Group 18) tolerances of 0.02 ppm are based on the low toxicological properties of spinosad and the proposed use pattern (mound treatment for fire ants); watercress and cilantro leaf are based on the leafy vegetable tolerance (Crop Group 4, 8 ppm); turnip tops and ti palm are translated from the brassica leafy vegetables tolerance (Crop Subgroup 5B, 10 ppm); and sugar apple, cherimoya, atemoya, custard apple, ilama, soursop, biriba, lychee, longan, spanish lime, rambutan, pulasan, papaya, star apple, black sapote, mango, sapodilla, canistel, mamey sapote, avocado, guava, feijoa, jaboticaba, wax jambu, starfruit, passionfruit, acerola, and white sapote are translated from citrus (0.3 ppm).

In addition to agricultural uses, spinosad is also registered for residential use. While this use may result in non-dietary, oral exposure of children to spinosad, HED has not performed a quantitative risk assessment for this route of exposure because a qualitative analysis indicated that this route is not likely to result in exposure levels above HED's level of concern. HED performed a chronic dietary risk assessment (memo, M. Doherty, DP Barcode D258604, 8/18/99). Highly conservative Tier 1 exposure analysis from the Dietary Exposure Evaluation System (DEEM™) estimates that chronic dietary (food only) exposure will occupy 74% of the cPAD for children ages 1-6 years (the highest-exposed population subgroup). Exposure estimates for all adult populations are less than 39% of the cPAD. The primary contributor to chronic dietary exposure is milk, which alone occupies 30% of the cPAD for children 1-6 yrs. Based on dietary (food only) exposures HED has back-calculated Drinking Water Levels of Comparison (DWLOCs) for spinosad. The DWLOCs range from 70 µg/L to 620 µg/L; these values are well above the chronic Tier II estimated environmental concentration of 0.092 µg/L. Although exposure to spinosad via drinking water may occur, it is not expected to exceed the calculated DWLOCs for any population subgroup. **Thus, aggregated risk from exposure to spinosad is below the Agency's level of concern for adults, infants, and children.**

HED recommends establishing permanent tolerances for spinosad as follows:

Cucurbit Vegetables (Crop Group 9)	0.30	ppm
Edible-podded Legume Vegetables (Crop Subgroup 6a)	0.30	ppm
Soybean	0.02	ppm
Stone Fruits (Crop Group 12)	0.20	ppm
Corn, Grain, Including Field, Sweet (K+cwhr), and Pop	0.020	ppm
Sorghum, Grain	1.0	ppm
Wheat, Grain	0.020	ppm

Forage, Fodder, Hay, Stover, and Straw of Cereal Grains	1.0	ppm
Aspirated Grain Fractions	20	ppm
Poultry, Meat, Meat Byproducts, and Eggs	0.020	ppm
Poultry, Fat	0.20	ppm
Oats	0.020	ppm
Barley	0.020	ppm
Buckwheat	0.020	ppm
Rye	0.020	ppm
Pearl Millet	1.0	ppm
Proso Millet	1.0	ppm
Grain Amaranth	1.0	ppm
Popcorn	0.020	ppm
Teosinte	0.020	ppm
Grass Forage, Fodder and Hay Crop Group (Crop Group 17)	0.020	ppm
Nongrass Animal Feeds Crop Group (Crop Group 18)	0.020	ppm
Watercress	8.0	ppm
Cilantro, Leaf	8.0	ppm
Turnip Tops	10	ppm
Ti Palm	10	ppm
Sugar Apple	0.30	ppm
Cherimoya	0.30	ppm
Atemoya	0.30	ppm
Custard Apple	0.30	ppm
Ilama	0.30	ppm
Soursop	0.30	ppm
Biriba	0.30	ppm
Lychee	0.30	ppm
Longan	0.30	ppm
Spanish Lime	0.30	ppm
Rambutan	0.30	ppm
Pulasan	0.30	ppm
Papaya	0.30	ppm
Star Apple	0.30	ppm
Black Sapote	0.30	ppm
Mango	0.30	ppm
Sapodilla	0.30	ppm
Canistel	0.30	ppm
Mamey Sapote	0.30	ppm
Avocado	0.30	ppm
Guava	0.30	ppm
Feijoa	0.30	ppm
Jaboticaba	0.30	ppm
Wax Jambu	0.30	ppm
Starfruit	0.30	ppm
Passionfruit	0.30	ppm

Acerola	0.30	ppm
White Sapote	0.30	ppm

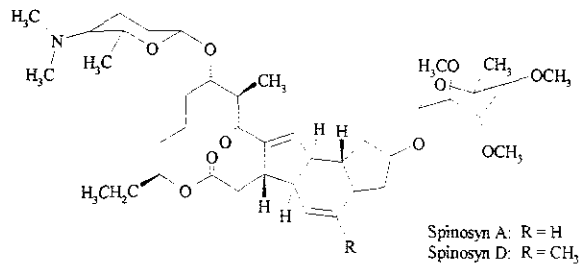
and revised tolerances for meat and milk:

Meat of Cattle, Goats, Hogs, Horses, and Sheep	0.15	ppm
Meat Byproducts of Cattle, Goats, Hogs, Horses, and Sheep	1.0	ppm
Fat of Cattle, Goats, Hogs, Horses, and Sheep	3.5	ppm
Milk, Whole	0.50	ppm
Milk, Fat	5.0	ppm.

Furthermore, HED recommends establishing conditional tolerances for:

Wheat, Flour, Bran, Middlings, and Shorts	0.15	ppm
Succulent Shelled Pea and Bean (Crop Subgroup 6b)	0.02	ppm
Dried Shelled Pea and Bean (Crop Subgroup 6c)	0.02	ppm

2.0 PHYSICOCHEMICAL PROPERTIES CHARACTERIZATION



Spinosad is a fermentation product of *Saccharopolyspora spinosa*. The product consists of two related active ingredients: **Spinosyn A** (Factor A; CAS# 131929-60-7) or 2-[(6-deoxy-2,3,4-tri-O-methyl-αϕ-L-manno-pyranosyl)oxy]-13-[[5-(dimethylamino)-tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-14-methyl-1H-as-Indaceno[3,2-d]oxacyclododecin-7,15-dione; and **Spinosyn D** (Factor D; CAS# 131929-63-0) or 2-[(6-deoxy-2,3,4-tri-O-methyl-αϕ-L-manno-pyranosyl)oxy]-13-[[5-(dimethyl-amino)-tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a, 16b-tetradecahydro-4,14-methyl-1H-as-Indaceno[3,2-d]oxacyclododecin-7,15-dione. Typically, the two factors are present at an 85:15 (A:D) ratio.

Both spinosyns are non-volatile, with vapor pressures of 2.4×10^{-10} and 1.6×10^{-10} mm Hg for Factors A and D, respectively. Water solubility of spinosad is dependent on both pH and the Factor of interest. Factor A is more soluble than Factor D and both are more soluble at lower pHs, as shown in Table 1. Because of its large size (molecular weight = 731 or 745 Daltons for Factors A and D, respectively), spinosad is not readily translocated across biological membranes, making it a non-systemic insecticide. While the parent compounds are rather stable in the absence of sunlight, exposure to light induces fairly rapid photolysis (half-lives on the order of 1 to 16 days). The products of photolysis are quickly broken down and incorporated into the general carbon pool. Thus, after treatment, spinosad will likely remain on treated surfaces where it will be rapidly degraded in the presence of sunlight.

Table 1. Physicochemical Properties of Spinosad Factors A and D.		
Property	**Spinosyn A**	**Spinosyn D**
Vapor Pressure, mm Hg	2.4×10^{-10}	1.6×10^{-10}
Melting Point, °C	84 - 100	161 - 170
Water Solubility, ppm pH 5 pH 7 pH 9	 290 235 16	 28.7 0.332 0.053

3.0 HAZARD CHARACTERIZATION

Summarized in Table 1 are the toxicological endpoints for spinosad. For a complete hazard characterization, please see HED's previous Human Health Risk Assessment for Spinosad (G. J. Herndon, *et al.*, 4/21/99, DP Barcodes D237013, D242939, D242941, D243796).

HED's FQPA Safety Factor Committee met on April 26, 1999 and recommended that the 10x Safety Factor to account for enhanced sensitivity of infants and children be reduced to 1x (i.e., removed). This recommendation is based on (1) the completeness of the toxicological database, (2) no indication of increased susceptibility of rat or rabbit fetuses to *in utero* and/or postnatal exposure, and (3) no requirement for a developmental neurotoxicity study.

Table 1. Summary of Toxicological Endpoints for Spinosad (HIARC, 1/22/98)			
EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT	STUDY
Acute Dietary	None	No appropriate endpoint available; risk assessment not required	
Chronic Dietary	NOEL=2.68 UF = 100	systemic toxicity.	Chronic Toxicity - Dog
	FQPA SF = 1x	RfD = 0.027 mg/kg/day **cPAD = 0.027 mg/kg/day**	
Short-Term (Dermal)	None	No appropriate endpoint available. No dermal absorption expected based on lack of toxicity at 2000 mg/kg/day as well as molecular structure and size.	
Intermediate-Term (Dermal)	None	No appropriate endpoint available. No dermal absorption expected based on lack of toxicity at 2000 mg/kg/day as well as molecular structure and size.	
Long-Term (Dermal)	None	No appropriate endpoint available; use pattern does not indicate a need for this risk assessment	
Inhalation (Any Time Period)	None	The low toxicity, use pattern and application rate does not indicate a need for risk assessment via this route.	

4.0 EXPOSURE ASSESSMENT

4.1 Summary of Registered Uses

Spinosad is an insecticide of the Naturalyte class of compounds developed by Dow-Elanco. It is highly active against target insect pests, but has low toxicity to mammals and most non-target insects. Spinosad has a novel mode of action. It is believed to act by prolonging activity of the neurotransmitter acetylcholine, but without affecting the activity of acetylcholinesterase (Salgado, V.L., 1997. "The modes of action of spinosad and other insect control products." *Down to Earth.* **52**(1):35-43).

Spinosad is registered for use on a number of agricultural commodities, including apples, Brassica vegetables, and fruiting vegetables (excluding cucurbits). Additionally, spinosad is registered for pest control in turfgrass and ornamental plants. There is a pending registration for spinosad use on tuberous and corm vegetables (PP8E5034) and a pending Section 18 use for control of Mediterranean fruit fly (99DA0009). Registered formulations of spinosad are Success, SpinTor, Tracer, and Conserve. These formulations vary from 1 to 4 lb ai/gallon and may be broadcast, band, or aerially applied. Application rates range from 0.023 to 0.156 lb ai/A, depending on the target pest and the crop. The maximum seasonal application rate is 0.45 lb ai/A. Application intervals are specified as being dependent on the pest populations or as a set number of days, ranging from 3 to 14, depending on the crop. There are label restrictions against too many applications per season and/or pest generation, to avoid development of pest resistance. Pre-harvest intervals range from 1 to 28 days, depending on the crop.

4.2 Dietary Exposure

The residue of concern for spinosad is parent spinosad (as specified in 40 CFR 180.495), which is made up of Spinosyn Factors A and D. Because of the non-systemic nature of spinosad, these residues are primarily found on the surfaces of treated commodities.

Adequate field trials were completed with cucumber, muskmelon, and squash (cucurbit vegetables); snap beans, snow peas, and soybean (legume vegetables); cherries, peaches, plums, and prunes (stone fruits); and sweet corn, field corn, sorghum, and wheat (cereal crops). The field trials and a poultry feeding study support the establishment of tolerances as follows (memo, M. Doherty, D249374, 6/24/99):

Cucurbit vegetables (Crop Group 9)	0.30	ppm
Edible-podded legume vegetables (Crop Subgroup 6A)	0.30	ppm
Succulent shelled pea and bean (Crop Subgroup 6B) [Conditional]	0.02	ppm
Dried shelled pea and bean (Crop Subgroup 6C) [Conditional]	0.02	ppm
Soybean	0.02	ppm
Stone fruits (Crop group 12)	0.20	ppm
Corn, grain, including field, sweet (K+CWHR), and pop	0.020	ppm
Sorghum, grain	1.0	ppm
Wheat, grain	0.020	ppm
Wheat, flour, bran, middlings, and shorts [Conditional]	0.15	ppm

Forage, fodder, hay, stover, and straw of cereal grains	1.0	ppm
Aspirated grain fractions	20	ppm
Meat of cattle, goats, hogs, horses, and sheep	0.15	ppm
Meat byproducts of cattle, goats, hogs, horses, and sheep	1.0	ppm
Fat of cattle, goats, hogs, horses, and sheep	3.5	ppm
Milk, whole	0.50	ppm
Milk, fat	5.0	ppm
Poultry, meat, meat byproducts, and eggs	0.020	ppm
Poultry, fat	0.20	ppm

Field trials for the legume vegetables did not include representative commodities from Crop Subgroups 6B (succulent shelled pea and bean) and 6C (dried shelled pea and bean). HED notes that IR-4 is planning on conducting spinosad field trials on commodities in Subgroups 6B and 6C this year. Until these studies are completed and considering the similarities between soybeans and commodities in those subgroups, HED is recommending for conditional tolerances on commodities in Crop Subgroups 6B and 6C. Tolerance-level residues of 0.02 ppm were assumed for these subgroups in this risk assessment.

Processing studies for wheat commodities were not submitted with the petition and were noted as a data deficiency in the residue chemistry review (memo, M. Doherty, D249374, 6/24/99). In the absence of processed commodity data, HED has use the maximum theoretical concentration factor of 8X for wheat, as listed in OPPTS Guideline 860.1520, to estimate residues in processed wheat commodities. A residue value of 0.15 ppm has been used for all processed wheat commodities for this risk assessment. Additionally, the residue chemistry review notes that the requested tolerances for aspirated grain fractions and ruminant commodities need to be revised. The HED-suggested tolerances have been used in this risk assessment as follows:

Aspirated grain fraction	20	ppm
Meat of cattle, goats, hogs, horses, and sheep	0.15	ppm
Meat byproducts of cattle, goats, hogs, horses, and sheep	1.0	ppm
Fat of cattle, goats, hogs, horses, and sheep	3.5	ppm
Milk, whole	0.40	ppm
Milk, fat	5	ppm

Provided results from field trials, processing studies and/or revised tolerance proposals do not result in tolerances higher than those used in this risk assessment, a revised assessment will not be needed upon receipt and review of those materials.

Based on the previously reached agreement between the Agency and IR-4 (memos, G. J. Herndon, DP Barcode D252416, 2/23/99; D258329, 8/4/99; D258330, 8/5/99), tolerances can be set for residues of spinosad in/on the following:

Oats	0.020	ppm
Barley	0.020	ppm
Buckwheat	0.020	ppm

Rye	0.020	ppm
Pearl Millet	1.0	ppm
Proso Millet	1.0	ppm
Grain Amaranth	1.0	ppm
Popcorn	0.020	ppm
Teosinte	0.020	ppm
Grass Forage, Fodder and Hay Crop Group (Crop Group 17)	0.020	ppm
Nongrass Animal Feeds Crop Group (Crop Group 18)	0.020	ppm
Watercress	8.0	ppm
Cilantro, Leaf	8.0	ppm
Turnip Tops	10	ppm
Ti Palm	10	ppm
Sugar Apple	0.30	ppm
Cherimoya	0.30	ppm
Atemoya	0.30	ppm
Custard Apple	0.30	ppm
Ilama	0.30	ppm
Soursop	0.30	ppm
Biriba	0.30	ppm
Lychee	0.30	ppm
Longan	0.30	ppm
Spanish Lime	0.30	ppm
Rambutan	0.30	ppm
Pulasan	0.30	ppm
Papaya	0.30	ppm
Star Apple	0.30	ppm
Black Sapote	0.30	ppm
Mango	0.30	ppm
Sapodilla	0.30	ppm
Canistel	0.30	ppm
Mamey Sapote	0.30	ppm
Avocado	0.30	ppm
Guava	0.30	ppm
Feijoa	0.30	ppm
Jaboticaba	0.30	ppm
Wax Jambu	0.30	ppm
Starfruit	0.30	ppm
Passionfruit	0.30	ppm
Acerola	0.30	ppm
White Sapote	0.30	ppm

4.2.1 Chronic Food Exposure

HED performed a chronic dietary exposure analysis (memo, M. Doherty, DP Barcode D258604, 8/18/99) using the Dietary Exposure Evaluation Model (DEEM). This model incorporates 3-day average 1989-1992 food consumption data from USDA's Continuing Survey of Food Intake by Individuals and accumulates exposure to the chemical for each commodity. Residue values used in the dietary analysis and relevant to this petition were addressed in Section 4.2. As spinosad has been shown to partition into milk fat, HED used data from the previously submitted animal feeding study to calculate a spinosad residue for skim milk. This value was used to set the residue level for milk-based water. The chronic dietary (food only) analysis represents a highly conservative estimate of dietary exposure to spinosad. HED has taken this into consideration as part of this human health risk assessment.

Estimates of chronic dietary (food only) exposure to spinosad and associated risk are shown in Table 3. Note that since the FQPA Safety Factor was reduced to 1x, the cPAD and the RfD are equal. Exposure estimates for all population subgroups except those specific to infants and children were similar to that of the general U.S. population (0.0092 mg/kg/day, 34% cPAD), ranging from 0.0073 mg/kg/day (27% cPAD) for seniors 55+ years to 0.0105 mg/kg/day (39% cPAD) for people of non-Hispanic/non-white/non-black origins. The similarity of the exposure estimates across these subgroups indicates that exposure to spinosad is not heavily affected by ethnic, seasonal, or regional dietary influences. Overall, the highest exposed population subgroup is children ages 1-6, whose exposure of 0.020 mg/kg/day occupies 74% of the cPAD. HED is typically not concerned with exposures that are less than 100% of the population adjusted dose, as this represents an exposure level for which adverse effects are not expected. **Chronic dietary (food only) risk is less than HED's level of concern.**

4.2.2 Water

Monitoring data depicting residue levels of spinosad in drinking water are not available. Therefore, HED cannot perform a quantitative risk assessment for drinking water exposure. Instead, HED had used modeled estimated environmental concentrations (EECs), provided by EFED, and back-calculated drinking water levels of comparison (DWLOCs) to determine whether exposure to spinosad via drinking water is likely to be of concern.

EFED concludes that the available data on spinosad shows that the compound is not mobile or persistent, and therefore has little potential to leach to ground water. Spinosad may however contaminate surface water upon the release of water from flooded fields to the environment. In order to assess drinking water exposures, EFED used the screening models PRZM and EXAMS to generate surface water EECs associated with application of spinosad to various crops. Modeled scenarios were selected because they are expected to represent roughly the upper 90th percentile for surface water vulnerability, given the chemical's geographic use range. The Tier 2 chronic surface water EEC for spinosad is **0.092 µg/L** and is based on application of the insecticide to cole crops (0.13 lb ai/A/application, 0.45 lb ai/A/season). The

EEC value is over 500 times less than the lowest DWLOC (Table 3). **Drinking water is not expected to be a significant source of exposure to spinosad.**

Table 3. Summary of Chronic Dietary Exposure and Risk and Drinking Water Levels of Comparison for Spinosad.

Population Subgroup[1]	Dietary Exposure, mg/kg/day[2]	% cPAD[3]	Max. H_2O Exposure, mg/kg/day[4]	DWLOC, µg/L[5]	EEC, µg/L[6]
U.S. Population (total)	0.00915	34	0.01785	620	0.092
Non-Hisp/non-white/non-black	0.01046	39	0.01654	580	0.092
Children 1-6 yrs	0.01998	74	0.00702	70	0.092
Females 13+ (nursing)	0.00951	35	0.01749	520	0.092

[1] The population subgroups shown are the U.S. population, the non-Hispanic/non-white/non-black subpopulation (whose estimated exposure is greater than that of the U.S. population), and the subpopulations within the children and female subgroups with the highest exposure.
[2] Tier 1 dietary (food only) estimated exposure to spinosad.
[3] % cPAD = Dietary Exposure (mg/kd/day)/(chronic RfD (mg/kg/day) ÷ FQPA Safety Factor).
[4] Maximum Water Exposure = cPAD (mg/kg/day) - Dietary Exposure (mg/kg/day).
[5] DWLOC = Drinking Water Level of Comparison = Maximum Water Exposure (mg/kg/day) × body weight (70 kg males, 60 kg females, 10 kg children) ÷ water consumption (2 L/day adults, 1 L/day children) × 10^3 µg/mg. Values expressed to 2 significant figures
[6] EEC = Estimated Environmental Concentration. Values are Tier 2 chronic estimates for surface water.

4.3 Occupational Exposure

As shown in Table 1, the HIARC was not concerned with dermal or inhalation routes of exposure for spinosad; thus, an occupational exposure assessment is not required. For a complete characterization, please see HED's previous Human Health Risk Assessment for Spinosad (G. J. Herndon, *et al.*, 4/21/99, DP Barcodes D237013, D242939, D242941, D243796).

4.4 Residential Exposure

No acute dietary, cancer, or short-, intermediate-, or chronic-term dermal or inhalation endpoints were identified by HIARC.

Registered residential uses for spinosad currently include *Conserve SC Turf and Ornamental* (EPA Reg# 62719-291) and *Conserve Fire Ant Bait* (EPA Reg# 62719-291). Both products are registered for outdoor use only.

The turf/ornamental and fire ant bait uses may result in non-dietary ingestion of spinosad-treated plant material or soil by children. Half-life estimates for spinosyn A on various plant foliage ranges from 1.6 to 16 days and generally is dependent on the amount of sunlight received on the plant surfaces.

To calculate a quantitative risk from a potential ingestion of grass (in the absence of acute-, short-, or intermediate-term oral endpoints), RAB2 would need to default to the chronic dietary endpoint. This scenario would represent a child eating grass for > 6 months continuously. Based on the low application rate for spinosad on turf (0.41 lbs.ai./A.), its non-systemic nature, its short half- life (especially in sunlight), and the rapid incorporation of spinosad metabolites into the general carbon pool; RAB2 believes that residues of spinosad on turf/ornamentals and soil after application would be low and decrease rapidly over time. RAB2 believes that it is inappropriate to perform a quantitative dietary risk representing a chronic scenario from children ingesting spinosad-treated plants or soil. Qualitatively, the risk from children's ingestion of plant or soil as a result of turf/ornamental and fire ant bait uses does not exceed HED's level of concern.

5.0 AGGREGATE RISK ASSESSMENTS AND RISK CHARACTERIZATION

Conservative assumptions have been made throughout this risk assessment. Residue estimates used in the dietary assessment are at published, proposed, or suggested tolerance levels. The two exceptions to this are wheat processed commodities, which are based on a highly conservative maximum theoretical concentration factor, and milk-based water, which is conservatively based on a theoretical maximum residue concentration calculated for skim milk. Estimated concentration of spinosad in drinking water is also quite conservative. Because of the nature of the spinosad molecule, the low application rate, and need to use a chronic oral toxicological endpoint, HED does not believe it appropriate to aggregate the potential residential exposure to spinosad via turf grass with other oral (dietary + drinking water) exposures. As drinking water is not expected to be a significant route of exposure to spinosad, dietary (food only) exposure is the only route of concern. Thus, exposures to spinosad from its proposed uses on the subject-listed commodities, taken in conjunction with other registered and pending uses of spinosad, are below the Agency's level of concern.

6.0 DATA NEEDS

HED noted in the review of the residue chemistry data for petition 8F5002 that

- Processing studies are required for processed commodities of wheat. Upon receipt and review of those studies, HED will reassess the tolerances for wheat processed commodities.
- Field trial data are required for representative commodities of Crop Subgroups 6B and 6C. It is HED's understanding that these will be completed by IR-4 in the coming year. Upon receipt and review of those studies, HED will reassess the tolerances for Crop Subgroups 6B and 6C.
- A revised Section B is required that removes the possibility of broadcast treatments for fire ant control.
- A revised Section F is required with separate listings for Crop Subgroups 6A (at 0.3 ppm), 6B (at 0.02 ppm), 6C (at 0.02 ppm), and soybeans (at 0.02 ppm). Revisions are also needed for aspirated grain fractions (20 ppm); meat (0.15 ppm), meat byproducts (1 ppm), and fat (3.5 ppm) of cattle, goats, hogs, horses, and sheep; whole milk (0.5 ppm); milk fat (5 ppm); and wheat bran, flour, middlings, and shorts (0.15 ppm).

No other data gaps exist with respect to petition 8F5002. No data gaps exist with respect to petition 9E6035.

cc: M. Doherty, RAB2 Reading File, PP8E5034, PP9E6035